



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,812	06/20/2003	Frank Bonadio	08203.0030-01	7588

22852 7590 12/02/2008
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

BIANCO, PATRICIA

ART UNIT	PAPER NUMBER
----------	--------------

3772

MAIL DATE	DELIVERY MODE
-----------	---------------

12/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/600,812	Applicant(s) BONADIO ET AL.	
	Examiner PATRICIA M. BIANCO	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-40, 42-55, 73-85 and 87-110 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-40, 42-55, 73-85 and 87-110 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 June 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/5/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This action is in response to applicant's response filed 05/05/2008. Applicant amended the instant application as follows: claims 26-29, 31, 35, 38-40, 42-45, 47, 51, 54, 55, 73-76, 78, 82-85, 87-90, 92, 96-101, & 103 have been amended; claims 25, 41, 56-72 & 86 have been cancelled; and claims 105-110 have been added.

Applicant's amendments have necessitated new rejections under 35 USC 112, 1st and 2nd paragraphs and a new objection to the Specification and Drawings for Lack of Antecedent Basis for newly amended claim subject matter.

Response to Arguments

Applicant's arguments filed 05/05/2008 have been fully considered but they are not persuasive. Further, Applicant's arguments with respect to the priority claim have been considered but are not persuasive. Please note previous arguments in the Non-final dated 11/05/07 regarding the 102(e) rejection to Leahy (US 5,640,977).

Arguments to Non-Obviousness

Applicant again argues that Leahy does not disclose a "primary" coupling through the incision. The examiner respectfully disagrees. It is the position of the examiner that the device of Leahy does in fact provide a single coupling with the patient's body through the incision of only the ring and diaphragm as shown below in figure 19 (see body of 102 (e) rejection below). The adhesive layer in the Leahy device is not part of the coupling device nor is it needed for attaching the coupling to the body; it is taught to attach the surgical device to a drape (shown as D in figure 19). Further, applicant's claim construction includes the transition phrase "comprising" which is an open-ended limitation. Thus, the inclusion of the adhesive attaching a

Art Unit: 3772

drape to a patient is not precluded from the claim construction of the pending claims. In comparison to the Leahy patent, note that figure 19 in Leahy discloses a protector or tubular member (262) that is equivalent or an obvious variant of the claimed diaphragm, that has a distal and proximal end; the proximal end has ring that is an incision engaging portion (263) and a distal or outer ring (264). The sleeve (102) is a flexible gas-impermeable material that is closed at a distal end and open at a proximal end to receive a surgeon's hand or a surgical instrument through opening (114) of said sleeve. This sleeve has an opening (105) connected to the Distal ring (264) of the diaphragm and is seen to be equivalent to the claimed "entry seal assembly" as Leahy teaches that there is a controlled pressurized environment.

It is the position of the examiner that the Leahy device since the adhesive attachment of a drape to the coupler & to the body of the patient are not required by the invention but are merely an option for the surgeon or surgical team to have. Therefore, the engagement of the incision engaging portion to the incision & the outer engaging ring portion can be the only or "primary" coupling of the device to the skin since the Leahy reference discloses that the drape & adhesive-backed structures of one embodiment of the device. In column 7, lines 17-20, it is stated that "Following incision, but before using the apparatus, ring (263) is inserted through the incision, and flange (111) is adhesively attached to a drape." This is a teaching that the body of the drape is not required to attach or couple the protector to the incision, but rather a teaching that the protector is capable of being used without the drape & would therefore be the only coupling to the patient. Also, it is stated in the disclosure of Leahy in column 7, lines 35-39, it states: "Additionally, or alternatively, an adhesive-backed flange may be placed around the exit opening of the sleeve, and in some cases adhesive may be applied to the patient around the area of the incision where the sealing flange is to be attached." Further, applicant notes in the instant application disclosure that it the disclosed device may be attached to the body of a

Art Unit: 3772

patient by a technique that is similar to attaching a colostomy bag where the “annular, adhesive coated flange is applied to a patients skin such that the annulus encircles the access incision” and further that the “Adhesion may be assisted by the application of an adhesive surgical drape prior to making the incision” (see page 11, lines 3-8).

Benefit Under 35 USC 119(d)

As previously set forth, Applicant argues that the pending claims are not estopped under 37 CFR 41.127(a)(1). The examiner respectfully disagrees. Applicant’s filing of a continuing application with claims 26-40, 42-55 and 73-85, & 87-110 (equivalent to the previously pending claims 25-55 & 72-104) to the method of providing sealed access through an incision in a patient must be rejected as estopped on the merits by the applicant’s loss in the interference. Applicant’s filing of a continuing application with claims 26-40, 42-55 and 73-85, & 87-110 (equivalent to the previously pending claims 25-55 & 72-104) to the subject matter the method of providing a surgical device for providing sealed access through an incision in a patient would have been obvious in view of the subject matter of the count. The claims must be rejected as estopped on the merits by the applicant’s loss in the interference, since one skilled in the art would have recognized use of the device as set forth in the count would have resulted in the method steps of the newly presented method claims. As noted above, the position of the examiner is that the device of Leahy is a “single” coupling assembly and as such the claims of the instant application would have been supported by the disclosure of Leahy.

Applicant further argues that they are entitled to the priority date of at least Irish Patent Application No. 930649. The examiner respectfully disagrees. The Board of Patent Appeals and Interferences held that as a matter of law, the Party Bonadio, et al. is not entitled to the benefit of priority in their U.S. application of the earlier filed Irish applications and the PCT

Art Unit: 3772

applications, because the current named individuals, Bonadio and Reid, are not the same inventive entities as the individuals named in Party Bonadio et al.'s Irish and PCT priority applications. According to §201.15 of the MPEP:

“The foreign application may have been filed by and in the name of the assignee or legal representative or agent of the inventor, as applicant. In such cases, if the certified copy of the foreign application corresponds with the one identified in the oath or declaration as required by 37 CFR 1.63 and no discrepancies appear, it may be assumed that the inventors are entitled to the claim for priority. If there is a disagreement as to inventors on the certified copy, the priority date should be refused until the inconsistency of disagreement is resolved.” [Emphasis added]

See Motion under 37 C.F.R 1.633(g) in Interference No. 104,195.

Applicant's arguments under this section of the response are not persuasive. First, applicant notes that “to the extent that the withholding of the priority date being based upon estoppel, applicants showing of non-obviousness over Leahy renders the basis moot”. Indeed if applicant were claiming a novel and non-obvious variation of the invention defined by the count of the lost interference preceding the question of propriety of the priority claim would be viewed in a different light. However, as noted in the office action, the Office is not persuaded of non-obviousness over Leahy and the lost count; thus the basis is not moot.

Next, applicant submits In re Deckler (citation omitted) does not support withholding the priority date of the '649 application as the sole issue in Deckler, in applicants view, was whether the losing party in an interference proceeding is entitled to a patent covering claims the party admits are patentable indistinguishable from the claims involved in the interference. Here, applicant does not admit the claims are patentably indistinguishable but asserts patentable distinctness. Further applicant argues Deckles deals with preclusion as to claims and is silent as to preclusion as to priority under 35 USC 119(d). The examiner is not persuaded. In re Deckler stands for the proposition that a losing party is barred on the merits from seeking a

Art Unit: 3772

claim that would have been anticipated or rendered obvious by the subject matter of the lost count. Patentable distinctness of the instant claims from the lost count has not been established by applicant: thus the estoppel rejection has been maintained herein. Preclusion as to claims includes the preclusion as to priority under 35 USC 119 as the claims lost in the prior interference were not accorded the priority date. The same claims here can not be granted an older date in order to overcome a rejection based upon the patent of the winning party to the interference. In addition, it is noted that procedural estoppel also applies here in that a losing party is procedurally barred from seeking from the examiner relief that could have been – but was not – sought in the interference proceeding. 37 CFR 41.127(a)(1). Applicant did not challenge the determination that he was not entitled to the priority in the prior interference. In this inaction, future answers to this issue are waived. The time to flush out the issue of priority, with respect to the date of invention of the subject matter covered by and corresponding to the count awarded to Leahy, has past. Applicant can not circumnavigate the prior resolution by the filing of a continuation and asserting the priority when the same invention is being claimed. The winning part of a prior interference must be able to have confidence in the outcome of the proceeding and applicant's failure to take action, respond to, or appeal the prior decision/judgment in interference can not be overlooked herein.

Finally, applicant argues the decision to deny applicant's right to the priority date under 35 USC 119(d) came in the form of a decision on a preliminary motion and is not a final judgment for res judicata or estoppel purposes. In support applicant cites *Curtis Mfg. Co. Inc. v. Plasti-Clip Corp*, 933 F. Supp. 94, 103 (D. N. H. 1995). No copy of this decision was provided by applicant and the only references the examiner sees by searching the USPQ of this citation

Art Unit: 3772

appear unrelated.¹²³ Thus the examiner is unable to determine precisely applicant's position any deeper than the general principle that a decision on preliminary motion is not a final judgment. In response, in general the examiner notes decisions on motions become final when they are unchallenged or the challenges found unpersuasive. The final judgment as to the issue of priority in the prior interference proceeding was awarded to the senior party and not to applicant. Absent further precedent to the contrary from applicant, the argument is unpersuasive.

¹ As cited in *Flex Products Inc. v. BASF Corp.*, 47 USPQ2d 1380 (E.D. Mich. 1998) "Indeed, one court has gone so far as to suggest that attorney opinions in such cases may be "withh [e]ld until trial." *Curtis Mfg. Co. v. Plasti-Clip Corp.*, 933 F.Supp. 107, 118 (D.N.H. 1995), *rev'd on other grounds*"

² As cited in *Heidelberg Harris Inc. v. Loebach*, 46 USPQ2d 1948 (Fed. Cir. 1998) "Loebach attempts to distinguish *Arachnid* by arguing that the district court in that case did not actually rescind the original assignment, but merely ordered the patent to be assigned to *Arachnid*. We do not agree with Loebach's characterization of that case. The district court in *Arachnid* declared *Arachnid* "to have been" the owner of the invention from the outset, yet this court nonetheless rejected *Arachnid*'s argument that it was entitled to sue for infringement during the period before it obtained record title to the patent. *Id.* at 1579, 19 USPQ2d at 1517; see also *Curtis Mfg. Co. v. Plasti-Clip Corp.*, 933 F.Supp. 94, 101-02 (D.N.H. 1995)."

³ As cited in *J & J Manufacturing Inc. v. Logan*, 48 USPQ2d 1412 (E.D. Tex. 1998) "However, in *Curtis Manufacturing Co., Inc. v. Plasti-Clip Corporation*, the United States District Court of New Hampshire looked the *Arachnid* loophole squarely in the eye (even though jurisdiction was not in question). 933 F.Supp. 94 (D.N.H. 1995). There, the manufacturer of a plastic clip document holder device brought an action against its competitors for patent infringement, fraudulent procurement of patent, and various common-law tort claims. *Id.* In their final pretrial statement the plaintiffs indicated that if the patent in issue was indeed assigned to them, then they would seek damages for the time period which the defendant held legal title to the patent." And "*Curtis*, 933 F.Supp. at 101-102 (D.N.H. 1995) (emphasis added)." Also referenced "It is worth noting that the district court was reviewing a patent interference action previously brought in the Patent and Trademark Office; and, as a result of this procedural posture, jurisdiction in the federal court was not at issue."

Drawings

The drawings are objected to under 37 CFR 1.83(b) because they are incomplete. 37

CFR 1.83(b) reads as follows:

When the invention consists of an improvement on an old machine the drawing must when possible exhibit, in one or more views, the improved portion itself, disconnected from the old structure, and also in another view, so much only of the old structure as will suffice to show the connection of the invention therewith.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Newly presented claims 105-110 recite new claimed structures that are not shown in the claims. In claims 105-108, the following are not shown: the “pressurized environment inside the surgical device” is not shown and the “entry seal assembly” located proximal to the diaphragm.

Claim Objections

Claims 26, 42, 73 and 87 are object to because the claimed invention is attempting to claim non-statutory subject matter. The claims positively recite “includes at least part of a human arm”. A claim or claims directed to or including within its scope a human being or a part of a human being is not patentable subject matter (See 35 U.S.C. §101). The grant of a patent giving limited, but exclusive property right to a human being is prohibited by the Constitution. Therefore, it is suggested that any claim that would include a human being, or part thereof, within its scope should use “adapted to include at least a part of a human arm” or “adapted for including at least a part of a human arm” to define the metes and bounds of the claimed subject matter which is a permissible form of expression.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Newly presented claims 105-110 recite the following structures that do not have proper antecedent basis in the specification as originally filed. While Applicant has pointed to support on page 9, line 27 through page 10, line 4 and Figure 9 of the specification and drawings, the examiner disagrees there is antecedent basis for the following claimed structures:

- “an entry seal assembly”
- “controlled pressurized environment inside the surgical device”
- “distal ring”
- “primary coupling”

The disclosure is objected to because of the following informalities:

The amendment filed 5/5/08 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new

Art Unit: 3772

matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicant has added new claims 105-110 that recite limitations that do not have support in the originally filed disclosure. While Applicant has pointed to page 9, line 27 through page 10, line 4 and Figure 9 of the specification and drawings for the support of the new claim limitations, the examiner disagrees that these eleven lines & Figure 9 can be interpreted to provide support for the following structures & claimed functions:

In claim 105, the limitations of an entry seal assembly located proximal the tubular diaphragm and ***configured to maintain a controlled pressurized environment inside the surgical device*** and ***the engagement of the incision engaging portion to the incision and the distal ring to the internal body tissue forming a primary coupling of the surgical device*** is not supported.

In claims 106, the limitations of an entry seal assembly located proximal the tubular diaphragm and ***configured to maintain a controlled pressurized environment inside the surgical device such that the engagement of the incision engaging portion of the diaphragm with the incision and engagement of the distal ring to the internal body tissue increases in pressure within the controlled pressurized environment*** is not supported.

In claim 107, the limitations of an entry seal assembly located proximal the tubular diaphragm and ***configured to maintain a controlled pressurized environment inside the surgical device*** and the engagement of the distal ring to the internal body tissue providing ***a seal such that the incision engaging portion of the tubular diaphragm is not subject to the controlled pressurized environment, while the internal portion of the tubular diaphragm is subject to the controlled pressurized environment*** is not supported.

Art Unit: 3772

In claim 108, the limitations ***sealing a proximal end of the surgical device with an entry seal assembly; creating a controlled pressurized environment inside the surgical device*** is not supported.

In claim 109, the limitations ***inserting an object through the entry seal assembly and the diaphragm and into the patient, the controlled pressurized environment being maintained during the insertion of the object*** is not supported.

In claim 110, the limitations ***creating of a controlled pressurized environment inside the surgical device includes increasing the engagement of the diaphragm and distal ring with the incision and internal body tissue with an increase in pressure in the controlled pressurized environment*** is not supported.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

Art Unit: 3772

reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

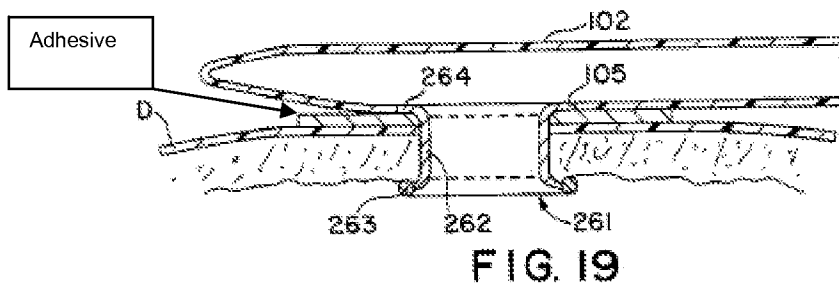
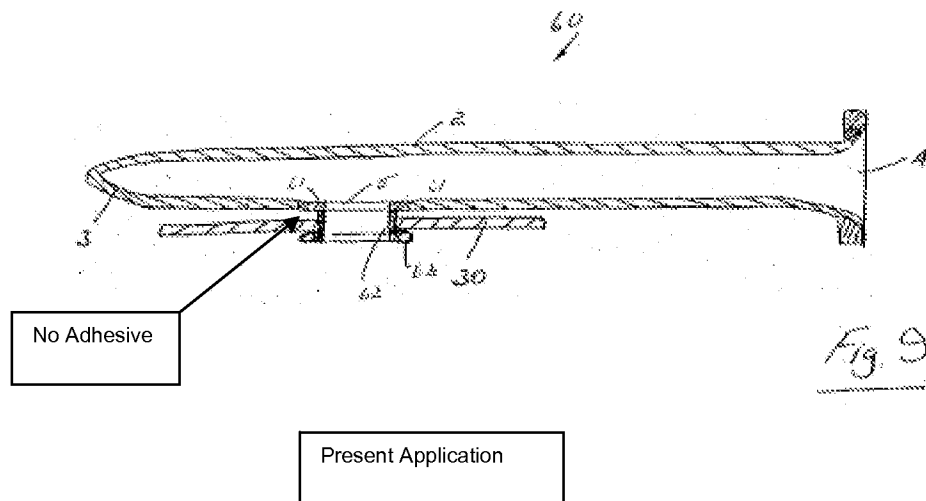
Claims 26-40, 42-55 and 73-85, & 87-110 are finally rejected under 35 U.S.C. 102(e) as being anticipated by Leahy (U.S. Patent No. 5,640,977). Leahy anticipates the claimed invention because of admissions made by Applicant during an interference proceeding, during an Examiner's Interview on March 23, 2005 and given the fact that Leahy was declared the winning party of the interference. Also, please note the previous arguments in the Non-final dated 11/05/07 regarding Leahy (US 5,640,977) as they apply to the claimed invention.

During the interview on March 23, Applicant and his attorney made the following admissions:

1) The new claims 26-40, 42-55 and 73-85, & 87-110 (equivalent to the previously pending claims 25-55 & 72-104) of the present application are directed only at the embodiment shown in Figure 9.

2) In comparison to the Leahy patent, the only difference between Figure 9 of the present invention and Figure 19 of the Leahy patent is that the Leahy patent includes an adhesive whereas Figure 9 of the present application does not illustrate an adhesive (see below).

Art Unit: 3772



U.S. Patent No. 5,640,977

The Office takes the position that the scope of the patented claims of Leahy are so broad they also cover a surgical device and method of providing sealed access through an incision without the use of an adhesive, as is evident by the claims. For instance, independent claims 1, 20, and 28 of the Leahy patent do not recite the limitation of an adhesive. The claims of the Leahy patent only recite the adhesive in dependent claims such as claims 6, 7, and 24. The patented claims, which do not mention the adhesive or depend upon such a claim, do not require the adhesive. Therefore, the patented claims of Leahy read upon Figure 9

Art Unit: 3772

of the present application and anticipate the of the present application. It is the Office's position that the claims of the present invention is directed to the same invention patentable invention lost during the interference. Since Leahy won the interference and it was ordered that the present invention is not entitled to a patent which covers the claims won by Leahy during the interference. The present invention is not entitled to a patent containing the claims corresponding to the count or counts of the interference as ordered by the Board's judgment.

Furthermore, during the interference, applicant admitted in Appendix A of the Amendment filed on January 5, 1997 that claim 28 of the Leahy patent reads upon Fig. 9. (A courtesy copy has been attached.) In order to invoke the interference, on page 6 of Appendix A, Applicant compared patented claim 28 to Fig. 9 of the present application. Applicant's comparison and analysis of patented claim 28 does not indicate that the adhesive or flange is required when interpreting the scope of this claim. Thus, Applicant acknowledges that the Leahy's device can be used without an adhesive and covers the embodiment of Figure 9 of the present application.

Furthermore, claims 26-40, 42-55 and 73-85, & 87-110 (equivalent to the previously pending claims 25-55 & 72-104) are directed to the subject matter the method of providing a surgical device for providing sealed access through an incision in a patient would have been obvious in view of the subject matter of the count, since one skilled in the art would have recognized use of the device as set forth in the count would have resulted in the method steps of the newly presented method claims. It is obvious to one having skill in the art that in order to provide a sealed access through an incision one must perform the claimed step of "making an incision in a patient" as well as the step of "providing a surgical device....." followed by the step of "inserting an object through an entry seal assembly coupled to the surgical device" as recited by the claims. The specific structure of the surgical device, as recited in the claims, is taught by

Art Unit: 3772

Leahy. As a result, the method as claimed would have been obvious when one of ordinary skill used the device of Leahy.

In comparison to the Leahy patent, note that figure 19 in Leahy discloses a protector or tubular member (262) that is equivalent or an obvious variant of the claimed diaphragm, that has a distal and proximal end; the proximal end has ring that is an incision engaging portion (263) and a distal or outer ring (264). The sleeve (102) is a flexible gas-impermeable material that is closed at a distal end and open at a proximal end to receive a surgeon's hand or a surgical instrument through opening (114) of said sleeve. This sleeve has an opening (105) connected to the Distal ring (264) of the diaphragm and is seen to be equivalent to the claimed "entry seal assembly" as Leahy teaches that there is a controlled pressurized environment.

It is the position of the examiner that the Leahy device since the adhesive attachment of a drape to the coupler & to the body of the patient are not required by the invention but are merely an option for the surgeon or surgical team to have. Therefore, the engagement of the incision engaging portion to the incision & the outer engaging ring portion can be the only or "primary" coupling of the device to the skin since the Leahy reference discloses that the drape & adhesive-backed structures of one embodiment of the device. In column 7, lines 17-20, it is stated that "Following incision, but before using the apparatus, ring (263) is inserted through the incision, and flange (111) is adhesively attached to a drape." This is a teaching that the body of the drape is not required to attach or couple the protector to the incision, but rather a teaching that the protector is capable of being used without the drape & would therefore be the only coupling to the patient. Also, it is stated in the disclosure of Leahy in column 7, lines 35-39, it states: "Additionally, or alternatively, an adhesive-backed flange may be placed around the exit opening of the sleeve, and in some cases adhesive may be applied to the patient around the area of the incision where the sealing flange is to be attached."

Art Unit: 3772

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Claims 26-40, 42-55 and 73-85, & 87-110 are finally rejected under 35 U.S.C. 102(g) over the sole lost count of Patent Interference No. 104,195.

Claims 26-40, 42-55 and 73-85, & 87-110 correspond to the subject matter of the sole count of Patent Interference No. 104,195, as to which a judgment adverse to the applicant has been rendered. A losing party is barred on the merits from seeking a claim that would have been anticipated or rendered obvious by the subject matter of the lost count. *In re Deckler*, 977 F.2d 1449, 24 USPQ2d 1448 (Fed. Cir. 1992); *Ex parte Tytgat*, 225 USPQ 907 (Bd. Pat. App. & Inter. 1985). See also MPEP §2308.03.

This rejection incorporates the principles of res judica and collateral estoppel as independent claims 1 are rejected as not patentably distinct from the subject matter of the lost count.

Applicant lost on priority for a count drawn to subject matter to a surgical device for providing sealed access through an incision in a patient. The Board's judgment automatically disposed of all of the applicant's claims corresponding to the count. Applicant's filing of a continuing application with claims 26-40, 42-55 and 73-85, & 87-110 (equivalent to the previously pending claims 25-55 & 72-104) to the subject matter to a surgical device for

Art Unit: 3772

providing sealed access through an incision in a patient must be rejected as estopped on the merits by the applicant's loss in the interference.

Further, applicant's claim(s) was held unpatentable during the interference. Applicant could have moved, but did not move, to amend the claim(s). Now, applicant has filed a continuing application with amended claims. The subject matter of the amended claims would have been anticipated or obvious in view of the sole count of the interferences and the claims must be rejected as procedurally estopped. Whether the amendment is sufficient to overcome the ground for unpatentability or not, the time to have amended the claim(s) was during the interference.

Applicant lost on priority for a count drawn to subject matter to a surgical device for providing sealed access through an incision in a patient. The Board's judgment automatically disposed of all of the applicant's claims corresponding the count. Applicant's filing of a continuing application with claims 26-40, 42-55 and 73-85, & 87-110 (equivalent to the previously pending claims 25-55 & 72-104) to the method of providing sealed access through an incision in a patient must be rejected as estopped on the merits by the applicant's loss in the interference. Applicant's filing of a continuing application with claims 26-40, 42-55 and 73-85, & 87-110 (equivalent to the previously pending claims 25-55 & 72-104) to the subject matter the method of providing a surgical device for providing sealed access through an incision in a patient would have been obvious in view of the subject matter of the count. The claims must be rejected as estopped on the merits by the applicant's loss in the interference, since one skilled in the art would have recognized use of the device as set forth in the count would have resulted in the method steps of the newly presented method claims.

Furthermore, no second interference should occur between the same parties on patentably indistinct subject matter. If the Board of Patent Appeals and Interferences held that

Art Unit: 3772

there is no interference-in-fact between the parties for the subject matter of the count, that holding may not be reopened in further examination. If a party that lost the earlier interference is again claiming the same invention as the count, the interfering claims should be rejected as estopped. See also MPEP §2308.03(c).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PATRICIA M. BIANCO whose telephone number is (571)272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-271-7143.

Art Unit: 3772

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Bianco
SPE
Art Unit 3772